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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/524,454	03/10/2000	Kristian Berg	697.013US1	5804

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/18/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/524,454

Applicant(s)

Berg et al.

Examiner

G.R. Ewoldt

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 22, 2002 and Jan 02, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11.5 6) ☐ Other:

DETAILED ACTION

1. Claims 1-11 are pending and being acted upon.
2. In view of Applicant's amendment and response, filed 1/02/02, the previous rejections made under the second paragraph of 35 U.S.C. § 112 regarding lack of antecedent basis, and the rejections made under the first paragraph of 35 U.S.C. § 112 regarding lack of adequate written description have been withdrawn.
3. The amendment filed 1/02/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: on page 16, the paragraph consisting of lines 27-34. Applicant has improperly changed the legend of Figure 4 describing said change as the correction of a typographical error. Absent a clear showing that original legend actually comprised a typographical error, said change comprises the introduction of new matter into the specification and is therefore impermissible.
4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1-11 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record as set forth in Paper No. 9, mailed 4/24/01.

Applicant's arguments, filed 1/02/02, have been fully considered but they are not persuasive. Applicant argues that "The MART-1 peptide is recognized in the literature as a molecule capable of stimulating an immune response *in vivo* and *in vitro*, and is known to be used in vaccines." Applicant provides 3 references in support of the argument. First note that while MART-1 has been used in vaccines, none of the vaccines have proven efficacious, thus MART-1 cannot be considered a well-known vaccine antigen as might be presumed from Applicant's argument.

The Examiner's position regarding the instant rejection, however, is not related to the antigenicity of any particular antigen, but rather to the lack of enablement in the instant specification for the method of the instant claims. Note that the references teach methods of peptide immunization, DNA immunization, and dendritic cell loading; none of the references teach methods of PDI. Thus, it is the Examiner's position that none of the references actually provide any support for the method of the instant claims.

Applicant argues "Thus, in light of the fact that Applicants disclose cell surface expression, i.e., antigenic presentation, of MART-1 via PCI, that MART-1 has been shown to induce an immune response, and is known as a vaccine antigen, it is respectfully requested that Applicants' specification fully enables the claimed invention." Note, it is the Examiner's position that the specification does not sufficiently disclose either cell surface expression or antigenic presentation as set forth in the previous Office action. Further, it is the Examiner's position that Applicant has not actually demonstrated, but merely asserts, the most critical aspect of the instant invention, i.e., the stimulation of an immune response. Thus, it remains the Examiner's position that the methods of the instant claims are unpredictable and would require undue experimentation.

Applicant argues "The Examiner is urged to consider that photodynamic therapy (PDT), discussed by Lynch et al., Sternberg et al., and Lapes et al. is a cytotoxic therapy which involves the killing of cells in which the photosensitizer is present by exposing them to light of an appropriate wavelength. See page 1, lines 24-page 4, line 1 of Applicants' specification. In contrast, claims 1-11 are directed towards the use of photochemical internalization (PCI). PCI does not depend upon cell killing (indeed, if the cells are killed then the method is ineffective), but PCI can be used, for example, as a method for introducing molecules, e.g., membrane impermeable molecules, into the cytosol of a cell which does not result in cell death (page 4, lines 2-21 of Applicants' specification). Thus, PCI is distinct from PDT." It is the Examiner's position that if PCI is performed, PDT will result, i.e., the methods of the instant claims will result in immunosuppression and cell killing.

Applicant provides three additional references which Applicant argues demonstrate that PDT can stimulate immunological responses. However, each of the references teach that PDT resulted in the death of the PDT treated cell. This cytotoxic

effect comprises a significant part of the rejection. It is clear that the method of the instant claims is not intended as a to be cytotoxic to the treated cells, see for example, page 5 of the specification where it is disclosed that the method induces internalization "without killing the cell," or Claim 5 wherein the method is used on antigen presenting cells (which presumably are intended to retain their viability). Thus, it appears that the references support the Examiner's position that the method as claimed must be considered highly unpredictable.

Applicant argues that Example 2 discloses the cell surface expression of the MART-1 peptide. Applicant is simply in error in this assertion, Example 2, the results of which are disclosed in Figure 3, discloses a cytotoxic cell assay as measured by ⁵¹Cr release. Neither the Example nor the Figure disclose cell surface expression. Further, it remains the Examiner's position that the experiment does not disclose all the necessary controls, i.e., a control absent the photosensitizing agent or a control for allo or irrelevant killing.

Applicant's argument that the results of Example 3, as set forth in Figure 4, were not allowed to continue for a sufficient time to actually demonstrate the cell surface expression of the antigen is insufficient to enable the methods of the instant claims. Regarding Applicant's attempt to amend the results of the experiment, see paragraph 3 above.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 6-8 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the abbreviations "TPPS₄, TPPS_{2a}, and AlPcS_{2a}" render the claim indefinite because they have not been defined in claim 8, as set forth in Paper No. 9, mailed 4/24/01.

Applicant has not argued against this rejection.

8. No claim is allowed.

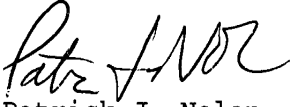
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 at (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
June 17, 2002


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600